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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,767	06/06/2005	Yuki Endo	Q88255	5081
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EXAMINER				
LEE, JAE W				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,767

Applicant(s)

ENDO ET AL.

Examiner

JAE W. LEE, PhD

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 7 and 11 is/are allowed.
- 6) ☒ Claim(s) 3-5 and 8 is/are rejected.
- 7) ☒ Claim(s) 6, 9 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

In response to the previous Office actions, a non-Final rejection (mailed on 09/25/2007), Applicants filed a response and amendment received on 12/26/2007. Said amendment, amended Claims 3-6, 8, 9 and 11, canceled Claim 10, and added Claim 12. Claims 1-9, 11 and 12 are at issue and present for examination.

Applicants' arguments filed on 12/26/2007, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

Claims 6, 8, 9 and 12 are objected to because of the following informalities:

Claim 6 recites "transformed with an expression vector of claim 4" which can be improved with respect to form. The Examiner suggests replacing the noted phrase with ---transformed with the expression vector of claim 4---.

Claim 8 recites "binds to Ak2 to (b) Akt2" which can be improved with respect to form so that it is consistent with the language in Claim 6 which Claim 8 depends from. The Examiner suggests replacing the noted phrase with ---binds to Ak2 with (b) Akt2---.

Claim 8 recites "(a)" and "(b)" which can be improved with respect to form so that it does not create confusion with the same "(a)" and "(b)" recited in Claim 6, which Claim 18 depends from. The Examiner suggests either deleting "(a)" and "(b)" or replace them with ---(i)--- and ---(ii)---, respectively in Claim 8.

Claims 9 and 12 are objected to for depending from a rejected Claim 8.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Claims 3-5 recite the phrase, "a polynucleotide encoding a polypeptide which comprises the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4 and which binds to Akt-2 or a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4" which is unclear and indefinite. It is unclear with respect to what "a polynucleotide" must encode. For instance, must "a polynucleotide" encode **a polypeptide which comprises the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4** and which *binds to (1) Akt-2 or (2) a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4?* Or must "a polynucleotide" encode **(1) a polypeptide which comprises the amino acid sequence of SEQ ID NO:2 or SEQ ID**

Art Unit: 1652

NO:4 and which binds to Akt-2 or (2) a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 or (3) SEQ ID NO:4?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of [compositions or methods], it must be clear that: (1) the identifying characteristics of the claimed [compositions or methods] have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

With regard to Claim 8, which recites the phrase, "a step of measuring a change in Akt2 based on the change in the aforementioned binding," the disclosure of the specification is limited to measuring binding of SEQ ID NO: 2 or 4 with Akt2. As such,

this is inadequate written description for Claim 8 because Claim 8 encompasses a step of measuring any change in Akt2 based on the change in the aforementioned binding. For instance, "a change in Akt2" could mean (1) a change in 3-D conformation of Akt2, (2) a change in the post-translational modification, (3) a change in the enzymatic activities, etc, all of which are widely variant methods having many different active method steps. Please refer to the M.P.E.P. section 2163 [R-5] under II, A, 3, (a), (ii) for more details with respect to sufficient number of representative species that should be disclosed to describe a widely variant genus.

Given the lack of additional representative species of a genus of methods that measures any change in Akt2, as encompassed by the claim, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for a method of measuring binding of SEQ ID NO: 2 or 4 with Akt2, does not reasonably provide enablement for any method of measuring any change in Akt2 as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 8 and 9 are so broad to encompass any method of measuring any change in Akt2. However, the disclosure of the specification is limited to measuring binding of SEQ ID NO: 2 or 4 with Akt2. As such, Applicants have not provided adequate guidance with respect to practicing methods of Claim 8 because Claim 8 encompasses a step of measuring any change in Akt2, which includes measuring (1) a change in 3-D conformation of Akt2, (2) a change in the post-translational modification, (3) a change in the enzymatic activities, etc, all of which are widely variant methods having many different active method steps. Therefore, the scope of the claimed invention is not commensurate with the guidance provided in the specification.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of measuring any change in Akt2 based on the change in its binding with SEQ ID NO: 2 or 4 so that one of skill in the art can identify a substance that inhibits their binding, is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

Claim 6 is rejected under 35 U.S.C. § 102(b) as being anticipated by Mitsuuchi et al. (Identification of a chromosome 3p14.3-21.1 gene, *APPL*, encoding an adaptor molecule that interacts with the oncoprotein-serine/threonine kinase AKT2, Oncogene, 1999, 18, 4891-4898).

The rejection was stated in the previous office action as it applied to previous claims 6 and 8. In response to this rejection, Applicants amended claims 6 and 8, and traverse the rejection as it applies to the newly amended claims.

Applicants argue that Mitsuuchi does not teach each and every element as set forth in the rejected claims. In particular, Mitsuuchi does not teach the use of a cell transformed with an expression vector comprising the polynucleotide encoding a polypeptide that comprises the amino acid sequence SEQ ID NO:2 or SEQ ID NO:4 and that binds to Akt-2 or a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. The reference of Mitsuuchi et al. teaches a yeast two-hybrid screening, wherein the human AKT2 is used as bait against proteins that are encoded by the human cDNA library (see pg 4897 under "Yeast two-hybrid screening"). Such screening assay method allows (i) a cell transformed with the expression vector comprising the cDNA from human cDNA library, which has the human AKT2, i.e., Applicants' SEQ ID NO: 4 of claim 1, to contact a substance to be tested, (ii) bind said proteins with AKT2, and (iii) select a substance which inhibits the protein-protein interaction. Therefore, for the reasons provided herein and in the previous office action, Claim 6 is anticipated by the teachings of Mitsuuchi et al.

Conclusion

Claims 3-6, 8 and 9 are not allowed for the reasons described above. Claim 12 are objected to for the reasons provided above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1652

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE, PhD/

Examiner, Art Unit 1656

/Richard G Hutson, Ph.D./

Primary Examiner, Art Unit 1652